K032330

3/2/04

8.0 510(k) SUMMARY (page 1 of 3)

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K032330

A. Safety and effectiveness information required per [§807.92(a)(1)]:

- **SUBMITTER'S NAME:** Thermo BioStar, Inc.
- **ADDRESS:** 331 South 104th Street, Louisville, CO 80027
- **TELEPHONE:** (303) 530-3888 ext. 612
- **FAX:** (303) 581-6405
- **CONTACT PERSON:** John G. Adams
- **DATE 510(k) SUMMARY PREPARED:** June, 2003

B. Safety and effectiveness information required per [§807.92(a)(2)]:

- **TRADE OR PROPRIETARY NAME:** CT OIA®
- **COMMON NAME:** Chlamydia antigen assay
- **CLASSIFICATION NAME:** Antigen, Enzyme Linked Immunoabsorbent Assay, Chlamydia

C. Identification of legally marketed device to which we are comparing performance.

- Thermo Biostar Chlamydia OIA

- Intended use of device [§807.92(a)(5)]:

The BioStar® brand CT OIA® assay is an Optical ImmunoAssay test for the rapid qualitative detection of chlamydia antigen from female endocervical swab specimens. This test is intended for *in vitro* diagnostic use as an aid in identifying the presence of *Chlamydia trachomatis* antigen. The assay is intended for use with symptomatic females in populations at risk for sexually transmitted diseases.

D. Description of device [§807.92(a)(4)]:

Principle of the Test:

The CT OIA test involves the qualitative extraction and detection of antigen specific to the Chlamydia genus. The Optical ImmunoAssay technology enables the direct visual detection of a physical change in the optical thickness of molecular thin films. This change is a result of antigen-antibody binding on an optical surface (silicon wafer). When an extracted specimen is placed directly on the optical surface, the immobilized specific antibodies capture the antigen. After washing, the substrate is added, increasing the thickness (mass enhancement) of the molecular thin film. This change in thickness alters the reflected light path and is visually perceived as a color change. Slight changes in optical thickness produce a distinct, visible color change. A positive result appears as a purple spot on the predominant gold background. When antigen is not present in the specimen, no binding takes place. Therefore, the optical thickness remains unchanged and the surface retains the original gold color indicating a negative result.

8.0 510(k) SUMMARY (page 2 of 3)

DEVICE COMPARISON:

The CT OIA assay is similar to the Chlamydia OIA assay method in that:

- Both assays are rapid diagnostic tests that utilize Optical Immunoassay technology
- Both assays are used to detect and identify lipopolysaccharide antigen specific to Chlamydia genus.
- Both assays detect lipopolysaccharide antigen specific to Chlamydia genus in female endocervical swabs
- Both assays can provide results in less than 30 minutes.
- Both assays are qualitative.

The CT OIA assay differs from the currently marketed Chlamydia OIA in that:

- CT OIA assay procedure has been revised and streamlined from that recommended for the original Chalamydia test.
- The CT OIA test clinical performance has been compared to the LCR (Ligase Chain Reaction) assay as a reference method, whereas the original test was compared against microbiology culture.

SUMMARY OF PERFORMANCE DATA:

CLINICAL STUDIES

Performance characteristics for the CT OIA assay were initially established in a multicenter study at four geographically diverse clinical sites.

H. Summary of clinical testing [§807.92(b)(2)]:

Reproducibility

Swab: Reproducibility testing was conducted at three physician office laboratories. Swab testing was performed on three blinded panels at three separate times at each institution. External kit positive and negative controls were also included in the study. There were no significant differences in performance among the sites. Overall reproducibility was 87.7% for the blinded samples (71/81), and 100% for the external control samples (18/18).

Clinical Sensitivity and Specificity

A study was conducted comparing the CT OIA test to a commercially available LCx nucleic acid amplification test for *C. trachomatis*. Secondary confirmation testing of positive LCx or positive OIA was done by a commercially available PCR test. A total of 1725 patients were enrolled into a multicenter study testing for both chlamydia and gonorrhoeae antigens, in male and female patients. For the purposes of this submission, data is presented from the 885 female patients enrolled. A total of 118 patients were excluded during the analysis, resulting in data from a total of 767 asymptomatic and symptomatic female patients included in the final analysis.

The CT OIA assay was evaluated versus LCx at four clinical trial sites (central hospital labs) located in the Northwest, Midwest, Mid-Atlantic and Southeast regions of the United States. A total of 885 female patients suspected of having, or with a history of *C. trachomatis* were evaluated by the CT OIA test as compared to the LCx test method. Data for the symptomatic enrollees (499) are presented in support of this submission. Sensitivity and specificity for symptomatic female endocervical swabs was 73.8% and 98.4% respectively. Overall PPV and NPV for symptomatic females was 87.3% and 96.2% respectively.

I. Conclusions from nonclinical / clinical testing [§807.92(b)(3)]:

The results of the above described internal and external studies demonstrate that the CT OIA test is as safe and effective as the comparative device.

J. Additional information [§807.92(d)]:

No additional information has been requested by FDA at this time.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR - 2 2004

Mr. John G. Adams
Thermo BioStar Regulatory Affairs
Thermo Electron Corporation
331 South 104th Street
Louisville, CO 80027

Re: k032330
Trade/Device Name: CT OIA®
Regulation Number: 21 CFR 866.3120
Regulation Name: Chlamydia Serological Reagents
Regulatory Class: Class I
Product Code: LJC
Dated: December 19, 2003
Received: December 22, 2003

Dear Mr. Adams:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

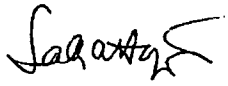
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K032330

Device Name: CT OIA®

Indications For Use:

The Thermo Electron CT OIA assay is an Optical ImmunoAssay (OIA) test for the rapid, qualitative detection of chlamydial antigen from female endocervical swab specimens. This test is intended for *in vitro* diagnostic use as an aid in identifying the presence of *Chlamydia trachomatis* antigen. The assay is intended for *in vitro* diagnostic use with symptomatic females in populations at risk for sexually transmitted diseases.

CT OIA test results are presumptive evidence for either the presence or absence of *C. trachomatis*. Definitive laboratory evidence for the presence/ absence of *C. trachomatis* would need additional testing. CT OIA test results should not preclude empiric treatment of women with overt symptoms of PID. Performance for use in asymptomatic male and female populations has not been established.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K032330